

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 8/18/04

Signature: Paula Depelteau

(Paula Depelteau)

Docket No.: CWRU-P03-003
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Markowitz et al.

Application No.: 10/649,591

Confirmation No.: 4997

Filed: August 26, 2003

Art Unit: N/A

For: METHODS AND COMPOSITIONS FOR
CATEGORIZING PATIENTS

Examiner: Not Yet Assigned

PETITION UNDER 37 C.F.R. 1.53(E)

MS Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice of Omitted Items mailed June 18, 2004, Applicants file this petition under 37 C.F.R.1.53(e).

The Notice of Omitted Items states that page 17 has been omitted from the specification. Applicants respectfully assert that page 17 was filed at the PTO as of the effective filing date of August 26, 2003.

As evidence that the application, including page 17, was deposited with the PTO, Applicants enclose a copy of the itemized return receipt postcard, date stamped August 26, 2003 (Exhibit A). There is no indication on the postcard that page 17 is omitted. Therefore, Applicants maintain that the PTO received the patent application with page 17 included. See MPEP §503.

A copy of page 17 as filed is enclosed (Exhibit B). It is Applicants' standard procedure to prepare an internal record copy of the patent application as filed, at the time of filing. The enclosed page 17 is an exact duplicate of page 17 as found in the internal record copy.

08/20/2004 YPOLITE1 00000058 181945 10649591

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In addition, Applicants note that page 17 is merely a description of figures 36 through 39 as filed. Accordingly, Applicants submit that, even if this petition is denied, the inclusion of page 17 in the application would not constitute new matter.

Applicants note that the return receipt postcard includes a writing from the PTO suggesting that the "first page of spec [is] missing". Applicants believe that the first page of the specification was duly filed with the PTO. Given that the present Notice of Omitted Items is silent with respect to page one, Applicants presume that the PTO now considers page one to have been properly filed.

Please charge our Deposit Account No. 18-1945 in the amount of \$130.00 covering the fee set forth in 37 CFR 1.17(h). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. CWRU-P03-003. A duplicate copy of this paper is enclosed.

Dated: August 18, 2004

Respectfully submitted,

By 

John D. Quisel

Registration No.: 47,874

ROPES & GRAY LLP

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Attorneys/Agents For Applicant

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PTO/SB/17 (10-03)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2004 <small>Effective 10/01/2003. Patent fees are subject to annual revision.</small>		Complete if Known	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Application Number	10/649591
TOTAL AMOUNT OF PAYMENT (\$)		Filing Date	August 26, 2003
130.00		First Named Inventor	Sanford D. Markowitz
		Examiner Name	Not Yet Assigned
		Art Unit	N/A
		Attorney Docket No.	CWRU-P03-003

METHOD OF PAYMENT (check all that apply)		FEE CALCULATION (continued)	
<input type="checkbox"/> Check <input type="checkbox"/> Credit Card <input type="checkbox"/> Money Order <input type="checkbox"/> Other <input type="checkbox"/> None		3. ADDITIONAL FEES	
<input checked="" type="checkbox"/> Deposit Account: Deposit Account Number: 18-1945 Deposit Account Name: Ropes & Gray LLP		Large Entity Small Entity	
The Director is authorized to: (check all that apply)		Fee Code Fee (\$)	
<input checked="" type="checkbox"/> Charge fee(s) indicated below <input checked="" type="checkbox"/> Credit any overpayments		Fee Code Fee (\$)	
<input checked="" type="checkbox"/> Charge any additional fee(s) or any underpayment of fee(s)		Fee Description	
<input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.		Fee Paid	
FEE CALCULATION			
1. BASIC FILING FEE			
Large Entity Small Entity			
Fee Code Fee (\$)			
1001 770 2001 385 Utility filing fee			
1002 340 2002 170 Design filing fee			
1003 530 2003 265 Plant filing fee			
1004 770 2004 385 Reissue filing fee			
1005 160 2005 80 Provisional filing fee			
SUBTOTAL (1) (\$)		0.00	
2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE			
Total Claims ** =		Extra Claims Fee from below Fee Paid	
Independent Claims ** =			
Multiple Dependent			
Large Entity Small Entity			
Fee Code Fee (\$)			
1202 18 2202 9 Claims in excess of 20			
1201 86 2201 43 Independent claims in excess of 3			
1203 290 2203 145 Multiple dependent claim, if not paid			
1204 86 2204 43 ** Reissue independent claims over original patent			
1205 18 2205 9 ** Reissue claims in excess of 20 and over original patent			
SUBTOTAL (2) (\$)		0.00	
**or number previously paid, if greater; For Reissues, see above			
		Other fee (specify)	
		*Reduced by Basic Filing Fee Paid	
		SUBTOTAL (3) (\$)	
		130	

SUBMITTED BY		(Complete if applicable)	
Name (Print/Type)	John D. Quisel	Registration No. (Attorney/Agent)	47,874
Signature		Telephone	(617) 951-7685
		Date	August 18, 2004

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Dated: 8/18/04 Signature: Paula Depelteau (Paula Depelteau)

Via: Express Mail: Airbill No. EV 324846093 US	Atty Dkt No.: CWRU-P03-003
Inventor: Sanford D. Markowitz	
Application No.: Not Yet Assigned	Filing Date: August 26, 2003
Title: METHODS AND COMPOSITIONS FOR CATEGORIZING PATIENTS	

Documents Filed:
Specification (74 pages) *first page of spec missing*

Drawings (48 sheets)

Preliminary Amendment (2 pages)

Unexecuted Oath or Declaration (4 pages)

Transmittal-New Utility Patent Application (1 page)

Application Data Sheet (2 pages)

Return-receipt postcard

00746 U.S. PTO
10/649591



Sender's Initials: JDQ/jm	Date: August 26, 2003
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Figure 36 shows a western blot of V5 tagged ColoUp2 protein detected by anti-V5 antibody. Lane 1: media supernate from SW480 colon cancer cells transfected with an empty expression vector. Lane 2: media supernate from ColoUp2-V5 expressing cells. Lane 3 : size markers. Lane 4 shows assay of serum from a mouse xenografted with control SW480 cells corresponding to lane 1. Lanes 5 and 6 show detection of circulating ColoUp2 proteins in blood from two mice bearing human colon cancer xenografts from ColoUp2-V5 expressing SW480 colon cells shown in lane 2. ColoUp2 is secreted as an 85KD and a companion 55KD size protein.

Figure 37 shows a western blot with anti-V5 antibody of V5 tagged ColoUp1 protein. Lane 1: media supernate from SW480 colon cancer cells transfected with an empty expression vector. Lane 2: media supernate from ColoUp1-V5 expressing SW480 cells. Lane 3 shows assay of serum from a mouse xenografted with control SW480 cells corresponding to lane 1. Lanes 4 shows detection of circulating ColoUp1 proteins in blood from a mouse bearing tumor xenografts from ColoUp1-V5 expressing SW480 cells shown in lane 2. Lane 5 : size markers.

Figure 38 shows, in the upper panel, the purification of ColoUp2 protein. Shown is a Coomassie blue staining of 250ng (lane 2a) and 500ng (lane 3a) of a purified ColoUp2 protein preparation. Size markers are in lane 1a. In the lower panel is shown a Coomassie blue stained gel showing purification of His-tagged ColoUp1 protein on Ni-NTA beads. Lane 1: markers, Lane 2 media from mock transfected cells, Lane 3 purification of media from ColoUp1 transfected cells. Clearly shown is purification to homogeneity of the 180kd ColoUp protein.

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Figure 39 shows, in the top panel, detection on an anti-V5 western of V5-tagged ColoUp2 protein. Lane 1: media from mock transfected Caco2 cells. Lane 2: detection of secreted ColoUp2 protein from transiently transfected Caco2 cells grown in standard culture dishes. Seen are the typical 85KD and 55KD secreted bands (the lane is heavily overloaded and minor degradation products are also visualized). Lane 3: molecular weight markers. Lanes 4-7: detection of ColoUp2 secreted into the basolateral

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/649,591	08/26/2003	Sanford D. Markowitz	CWRU-P03-003

CONFIRMATION NO. 4997

FORMALITIES LETTER



OC000000012985290

28120
 ROPES & GRAY LLP
 ONE INTERNATIONAL PLACE
 BOSTON, MA 02110-2624

Date Mailed: 06/18/2004



NOTICE OF OMITTED ITEM(S) IN A NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

A filing date has been accorded to the above-identified nonprovisional application papers; however, the following item(s) appear to have been omitted from the application:

- Page(s) 17 of the specification (description and claims).

I. Should applicant contend that the above-noted omitted item(s) was in fact deposited in the U.S. Patent and Trademark Office (USPTO) with the nonprovisional application papers, a copy of this Notice and a petition (and \$130.00 petition fee (37 CFR 1.17(h))) with evidence of such deposit **must** be filed within **TWO MONTHS** of the date of this Notice. The petition fee will be refunded if it is determined that the item(s) was received by the USPTO.

II. Should applicant desire to supply the omitted item(s) and accept the date that such omitted item(s) was filed in the USPTO as the filing date of the above-identified application, a copy of this Notice, the omitted item(s) (with a supplemental oath or declaration in compliance with 37 CFR 1.63 and 1.64 referring to such items), and a petition under 37 CFR 1.182 (with the \$130.00 petition fee (37 CFR 1.17(h))) requesting the later filing date **must** be filed within **TWO MONTHS** of the date of this Notice.

Applicant is advised that generally the filing fee required for an application is the filing fee in effect on the filing date accorded the application and that payment of the requisite basic filing fee on a date later than the filing date of the application requires payment of a surcharge (37 CFR 1.16(e)). To avoid processing delays and payment of a surcharge, applicant should submit any balance due for the requisite filing fee based on the later filing date being requested when submitting the omitted item(s) and the petition (and petition fee) requesting the later filing date.

III. The failure to file a petition (and petition fee) under the above options (I) or (II) within **TWO MONTHS** of the date of this Notice (37 CFR 1.181(f)) will be treated as a constructive acceptance by the applicant of the application as deposited in the USPTO. **THIS TWO MONTH PERIOD IS NOT EXTENDABLE UNDER 37 CFR 1.136(a) or (b).** In the absence of a timely filed petition in reply to this Notice, the application will maintain a filing date as of the date of deposit of the application papers in the USPTO, and original application papers (*i.e.*, the original disclosure of the invention) will include only those application papers present in the USPTO on the date of deposit.

In the event that applicant elects not to take action pursuant to options (I) or (II) above (thereby constructively electing option (III)), amendment of the specification to renumber the pages consecutively and cancel incomplete sentences caused by any omitted page(s), and/or amendment of the specification to cancel all references to any omitted drawing(s), relabel the drawing figures to be numbered consecutively (if necessary), and correct the

references in the specification to the drawing figures to correspond with any relabeled drawing figures, is required. A copy of the drawing figures showing the proposed changes in red ink should accompany with any drawing changes. Such amendment and/or correction to the drawing figures, if necessary, should be by way of preliminary amendment submitted prior to the first Office action to avoid delays in the prosecution of the application.

Replies should be mailed to: Mail Stop Missing Parts
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P.O. Box 1450
Alexandria VA 22313-1450

*A copy of this notice **MUST** be returned with the reply.*



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Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE